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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/380,738 12/06/99 REYNOLDS

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EXAMINER

HM22/0625

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LUKTON, D	
ART UNIT	PAPER NUMBER

1653

14

DATE MAILED:

06/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/380,738

Applicant(s)

Reynolds

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2001
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-40 is/are pending in the application.
- 4a) Of the above, claim(s) 1-6, 17-28, and 30-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-16, 39, and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Pursuant to the directives of paper No. 12 (filed 4/2/01), claim 29 has been cancelled, claims 1, 4, 5, 7, 9-13 amended, and claims 39-40 added. Claims 1-28, 30-40 are pending. Claims 1-6, 17-28, 30-38 remain withdrawn from consideration.

Claims 7-16, 39, 40 are examined in this Office action.

Applicants' arguments filed 4/2/01 have been considered and found persuasive. The previously imposed prior art rejections are withdrawn.

*

An abstract is required. Applicants have submitted an abstract. However, in directing addition of the abstract, applicants are communicating with personnel who are responsible for entering amendments, rather than with the examiner *per se*. The abstract should be submitted on a sheet of paper which contains no other amendments, and the amendment should make it clear the the abstract is being added, rather than amended. Currently, the phrase "in the abstract" is in use. This could be interpreted as a directive to amend an existing abstract, which is not the case. Resubmission of the abstract, and the statement directing its entry is required.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence

disclosures.

A CRF listing has been submitted, but contains errors, as indicated on the attached sheets.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 39 and 40 recite the term "anticariogenic". This term could be interpreted to mean that caries or cariogenesis can actually be prevented. However, there is no evidence that this is the case. Any of the following is suggested:

A composition comprising a delivery vehicle together with a complex according to

claim 7 in an amount effective to inhibit caries.

A composition comprising a delivery vehicle together with a complex according to claim 7 in an amount effective to inhibit cariogenesis.

A composition comprising a delivery vehicle together with a complex according to claim 7, wherein said delivery vehicle is adapted to co-localize calcium and phosphate ions at a target site, and wherein said complex is present in an amount effective to inhibit cariogenesis.

A composition which is useful to inhibit cariogenesis, comprising a delivery vehicle together with a complex according to claim 7.

*

Claims 7-16, 39-40 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 7 recites "or a derivative thereof". However, this renders the claims indefinite as to the possible derivatives.
- In claim 7, the appropriate "SEQ ID NO:" should be recited.
- Claim 8 recites the following:

"Ca₃(PO₄)₂ x H₂O , wherein x ≥ 1 "

However, it is not clear what "x" refers to. One option would be to recite the following: Ca₃(PO₄)₂ (H₂O)_n

- Claim 9 is drawn to a complex of claim 8, "further including" an additional component. As such, claim 9 is broader than claim 8; either claim 8 should be made sufficiently broad to encompass the subject matter of claim 9, or else claim 9 should be made independent.

- In claims 8-13, 39, 40, the term "complex" lacks antecedent basis.
- In claim 10, the following is present in SEQ ID NO: 2:
Arg-Glu-Leu⁸-Glu-Lu-...
However, there are typographical errors.
- In claim 10, each of the sequences is followed by a period. Each of these should be removed; of course, the claim should end in a period. In addition, the standard Markush Group format should be used (i.e., ...*selected from the group consisting of A, B, C and D*).
- In claim 11, there is a period following the peptide sequence, but no period at the end of the claim.
- Claims 12 and 13 are dependent on claim 11; however, each of claims 12 and 13 recite that "PP" represents a phosphopeptide. Unless the phosphopeptide of claims 12 and 13 is the same as that of claim 11, the claim dependence is improper. It is suggested that each of claims 12 and 13 be amended to recite that "PP" represents *said* phosphopeptide.
- Claim 15 should be written in independent form. In addition, the first step of the process should make reference to the peptide in question, i.e.:
(i) obtaining an aqueous solution of a phosphopeptide which has a pH of about 9.0, wherein said phosphopeptide includes the amino acid sequence Ser(P)-Ser(P)-Ser(P)-Glu-Glu SEQ ID NO: 5);
- Step (ii) of claim 15 should make reference to the solution of step (i), rather than (i) *per se*.
- Claim 15 should include a step for isolation of the final product. The following is suggested for the last two lines of claim 15:
(iv) drying the mixture of step (iii), and

(v) *isolating the stable alkaline calcium phosphate complex.*

- Claim 39 is rendered indefinite by its recitation of "including calcium and phosphate". Claim 39 is also rendered indefinite in that the delivery vehicle *per se* is said to comprise the active ingredient. However, if it comprises the active ingredients, it is more than just a delivery vehicle. Any of the following is suggested:

A composition comprising a delivery vehicle together with a complex according to claim 7 in an amount effective to inhibit caries.

A composition comprising a delivery vehicle together with a complex according to claim 7 in an amount effective to inhibit cariogenesis.

A composition comprising a delivery vehicle together with a complex according to claim 7, wherein said delivery vehicle is adapted to co-localize calcium and phosphate ions at a target site, and wherein said complex is present in an amount effective to inhibit cariogenesis.

A composition which is useful to inhibit cariogenesis, comprising a delivery vehicle together with a complex according to claim 7.

- In claim 40, the singular of each Markush Group member should be used, for consistency. In addition, "dairy" is misspelled. Also, the "dairy product" and "foodstuff" should be placed in a separate claim, since these Markush Group members are of another kind than the purely dental products. The following is suggested, along with claims 41 and 42:

The composition of claim ____ wherein said delivery vehicle is selected from the group consisting of toothpaste, toothpowder, a liquid dentifrice, mouthwash, a troche, chewing gum, dental paste, gingival massage cream, and a gargle tablet.

41. *A composition comprising a foodstuff together with a complex according to claim 7 in an amount effective to inhibit cariogenesis.*

42. *The composition according to claim 41, wherein said foodstuff is a dairy product.*

- It is suggested that applicants amend claim 1 to require the complex to be alkaline; alternatively claim 1 should be cancelled. (New matter, of course, should be avoided).
- It is suggested that applicants delete the phrase "treating or preventing" from line 1 of claim 25, and replace it with *inhibiting*, to avoid an enablement issue.
- It is suggested that applicants cancel claims 27 and 28, and add claims drawn to a method of promoting calcium absorption, or a method of providing bioavailable calcium in a patient afflicted with osteoporosis or osteomalacia.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800